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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,499	02/13/2002	Evangelyn C. Alocilja	MSU 4.1-587	4246

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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,499	ALOCILJA ET AL.	
	Examiner	Art Unit	
	Leon Y Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *4-6,11-13,15,17,20,23 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7-10,14,16,18,19,21,22,24 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *113 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040924*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-3, 7-10, 14, 16, 18-19, 21-22, 24, and 26 drawn to a biosensor device, classified in class 422, subclass 82.02.

   II. Claims 4-6, 11-13, 15, 17, 20-21, 23, and 25-26, drawn to a method for detecting an analyte in a fluid sample, classified in class 435, subclass 7.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used in the materially different process of liquid purification, wherein analytes in a sample flowing over the biosensor device bind to the capture reagents on the substrate, wherein the electrodes cause the substrate to increase in temperature, thereby destroying the bound analytes and purifying the sample.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Ian McLeod on 24 September 2004 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-3, 7-10, 14, 16, 18-19, 21-22, 24, and 26. Affirmation of this election must be made by applicant in replying to this Office action. Claims 4-6, 11-13, 15, 17, 20, 23, and 25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

7. The disclosure is objected to because of the following informalities: The section entitled "Description of Drawings" does not provide a description for Figures 1D and 1E.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3, 7-10, 14, 16, 18-19, 21-22, 24, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. In claims 1 and 7, lines 5 and 7, respectively, the phrase "bound to or as a moiety of the substrate" is vague and indefinite. The specification does not provide a definition for the phrase and it is unclear as to how a bound reagent is different from a moiety reagent of a substrate.

11. In claims 1, 7-8, and 14, lines 6 (claims 1 and 8) and 8 (claims 7 and 14), the phrase "spaced apart electrodes" is vague and indefinite. The specification does not provide a definition for the term and it is unclear as to what is meant by the term "spaced apart". Also, are they on the same side of the "defined area" (lines 6 and 8 of claims 1 and 7, respectively) or on different sides?

12. In claims 1 and 7, lines 12-13 and 14-15, respectively, the phrase "bound to or as a moiety of an electrically conductive polymer" is vague and indefinite. The specification does not provide a definition for the phrase and it is unclear as to how a bound reagent is different from a moiety reagent on a conductive polymer.

13. In claims 8 and 14, lines 13-16 and 15-18, respectively, the phrase "wherein when a fluid sample containing an antigen which is bound by the second antibody bound to the conductive polymer to form a complex" is vague and confusing. The phrase seems to be incomplete or missing elements. Currently, the phrase is confusing and it is not clear what is being claimed.

14. Claim 16 is vague and confusing. The entire claim seems to be incomplete and it is not clear what is being claimed. In addition, it is not clear whether the phrase "applied prior to being introduced into the second zone" (lines 3-4) applies to the limitation "third substrate (lines 1-2) or the limitation "fluid" (line 2).

15. In claims 18-19 and 21, lines 2-3 of the claims, the phrase "applied prior to being introduced into the second zone" is vague and indefinite. It is unclear whether the instant phrase applies to the limitation "pad" (line 1) or the limitation "fluid" (line 2). It is also unclear as to how either the "pad" or "fluid" is applied.

16. In claims 22, 24, and 26, lines 1-2 of the claims, the phrase "there is a multiple array" is vague and indefinite. Where is the multiple array located in the device? Is it in the first zone or second zone?

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-3, 7-10, 14, 16, 18-19, 21-22, 24, and 26 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kim et al (Biosensor & Bioelectronics 2000, 14:907-915).

In the instant claims, Kim et al reference teaches a system for detecting an analyte in a fluid sample which comprises (a) a biosensor device which comprises a strip of a substrate having at least two zones, wherein a (1) first of the zones contains a first antibody bound to the substrate in a defined area and spaced apart electrodes on either sides of the defined area, by disclosing a conductimetric immunosensor design comprising a middle section that contains screen-printed thick film electrodes in an interdigitated structure, wherein antibodies are immobilized on the interdigitated area (Figure 3 and caption) and the interdigitated structure also comprises silver electrodes,

wherein an anode and cathode are separated and the binding complex on the interdigitated structure is formed in between the electrodes (page 911, right column, 1st full paragraph, lines 1-5).

In the instant claims, Kim et al reference also teaches (2) a second of the zones containing a fluid transfer medium wherein the second zone comprises a second defined area containing a second antibody bound to an electrically conductive polymer, by disclosing that the immunosensor comprises a lower section that is defined with immobilized antibody-gold conjugates (Figure 3 and caption), wherein the lower section is a glass fiber membrane for sample application (Figure 1 and caption), and wherein the gold embodiment of the antibody-gold conjugates contain polyaniline as a conducting polymer (page 911, right column, 2nd full paragraph, lines 1-7 and Figure 4). The polyaniline polymer is considered to be a part of the gold particle and therefore the gold particle-polyaniline polymer complex is considered to be, as a whole, the conducting polymer that the antibody in Figure 4 attaches to in order to form the antibody-gold conjugate.

In the instant claims, Kim et al reference also teaches the limitation wherein when a fluid sample containing an antigen is bound by the second antibody bound to the conductive polymer to form a complex, the complex migrates to the first zone in the medium and the antigen is bound by the first antibody thereby altering a conductivity or resistance of the defined area in the first zone as measured between the electrodes, by disclosing that after the immuno-strips were placed in microwells, solutions within the microwells were absorbed from the bottom of the strips, wherein the medium dissolved

the gold conjugate, reaction between the conjugate and the analyte took place to produce a complex, the complex was carried up into the next membrane with the immobilized binder, and a second antigen-antibody reaction formed a sandwich-type immune complex at the sold surfaces, wherein a meter was used to measure the conductivities as responses of the immuno-strips with the electrodes to variable analyte concentrations (page 909, 2nd full paragraph, line 8 to page 910, left column, 1st paragraph, line 20).

In the instant claims, Kim et al reference also teaches (b) electrical means, and (c) measuring means of the first area before and after application of the sample in the second zone, by disclosing that voltage was applied across the electrodes (page 912, right column, 2nd full paragraph, lines 3-4) and that conductimetric detection was performed by a conductivity meter (page 910, left column, 1st paragraph, lines 5-8), wherein the measurements can determine a transient response after complex formation between antigen and antibody (page 912, right column, 2nd full paragraph, lines 1-3).

With regards to claims 2, 9, and 15, Kim et al reference teaches that the device further comprises a third zone adjacent to the first zone into which the fluid is absorbed after passing through the first defined area of the first zone, by disclosing a cellulose membrane that is an absorption pad as an upper section of the immunosensor strip (Figures 1 and 3, and captions).

With regards to claims 16, 18-19, and 21, Kim et reference teaches that a pad is applied prior to being introduced into the second zone, by disclosing microwells with sample medium into which the immuno-strips were placed (page 909, 2nd full paragraph,

lines 8-18; and Figure 1), as stated above. Since term "pad" has not been defined in the specification, the instant term is considered to be any substrate capable of containing a liquid sample medium.

Claim Rejections - 35 USC § 103

19. Claims 3, 10, 22, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Biosensor & Bioelectronics 2000, 14:907-915) in view of Roberts et al (US 5,958,791).

Kim et al reference has been disclosed above, but fails to teach that the first defined area has a dimension between the electrodes of 1.0 mm (claims 3 and 10), and fails to teach a multiple array (claims 22, 24, and 26).

Roberts et al reference teaches a test device that includes multiple sets of interdigitated electrode arrays, in order to perform simultaneous multiple analyte detection and assay a test sample for a plurality of analytes (column 18, lines 53-55 and column 25, lines 16-20), wherein the test device is a test strip with capillary flow through an absorbent material with a capture region (column 5, lines 29-42 and 55-56; and Figure 1), and wherein the capture region contains binding material that can be an antibody (column 11, lines 29-40).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Kim et al, with multiple sets of interdigitated electrode arrays, as taught by Roberts et al, in order to perform simultaneous multiple analyte

detection and assay a test sample for a plurality of analytes. One of ordinary skill in the art would have reasonable expectation of success in applying multiple sets of arrays, as taught by Roberts et al, in the device of Kim et al, since Kim et al teach a test strip with an interdigitated electrode array, and the device of Roberts et al is also a test strip, wherein the detection method includes interdigitated electrode arrays.

With regards to claims 3 and 10, Roberts et al reference also teaches that the actual area of interdigitation is 6mm x 1mm (column 24, lines 1-6).

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LYL

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09/30/04